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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,745	02/28/2002	Gary de Jong	24601-416C	8781

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,745

Applicant(s)

DE JONG ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-22,31,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,22,31 and 33 is/are rejected.
- 7) ☒ Claim(s) 18-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II (claims 17-22 and 31) in the response filed October 24, 2003 is acknowledged.

Acknowledgement is made of newly added claims 33 and 34.

Newly submitted claim 34 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the nature of the invention is a method for the identification of a test agent that delivers a nucleic acid into a cell, which properly would have been restricted into Group III of the original Election/Restriction requirement had the claim originally been present. This is evident from the final step, which requires an indication of "the ability of the [test] agent to deliver the nucleic acid into the cell." Thus, the method is not directed to the monitoring of a nucleic acids delivery into a cell, but to the indication of a *test agent's ability to cause the delivery* of the nucleic acid into a cell, and is a separate invention requiring a separate search and consideration. This is clearly indicated in the previous restriction requirement.

Accordingly, claim 34 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 17-22, 31, 33 and 34 are pending in the instant application. Applicant has canceled claims 1-16, 23-30 and 32. Claim 34 is withdrawn as being drawn to a non-elected invention. Claims 17-22, 31 and 33 are under examination in the instant application.

Priority

Applicant's claim to US Application No. 09/815,981 for domestic priority under 35 U.S.C. 120 is acknowledged.

It is noted that the first line of the specification indicates that the instant application is "related to" US Application No. 09/815,979. This is an improper claim to priority because there is no indication of the nature of the relationship between the instant application and US Application No. 09/815,979 (i.e., is it a continuation, etc.).

Furthermore, there is no indication of a priority claim to US Application No. 09/815,979 in the Oath, Application Data Sheet, or in the records of the USPTO. As such, priority to US Application No. 09/815,979 is not granted.

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/815,979, filed March 22, 2001. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national

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stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Information Disclosure Statement

The information disclosure statements filed October 30, 2002 (#1), January 21, 2003 (#2), April 14, 2003 (#3) and August 6, 2003 (#4) have been considered, and a signed and initialed copy of each form PTO-1449 has been attached to this Office Action.

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It is noted, however, that references AS through BC on IDS #1 have been crossed through. This is because these references contain browser executable code, which is not permitted for printing in a US Patent, should this application go to issue.

Specification

The disclosure is objected to because of the following informalities: the first line of the specification has an improper priority claim to US Application No. 09/815,979 because there is no indication of the nature of the relationship of the instant application to US Application No. 09/815,979. The reference must either be removed or corrected to indicate a proper relationship in order to bring the specification into compliance. Note that this will not officially lead to a granting of priority, absent a petition filed as set forth above.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the phrase “natural chromosome, an artificial chromosome, a fragment of a chromosome or naked DNA that is greater than about 0.6 megabase in size.” This phrase is indefinite because it is unclear if the limitation “greater than about 0.6 megabase in size” applies to each of the members of the Markush group, or if it applies to only the naked DNA. In the interest of compact prosecution, the claim is being

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interpreted broadly, where only the naked DNA is restricted to a size greater than about 0.6 megabase.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Felgner et al. (IDS #2 reference C; see entire document; henceforth Felgner).

Felgner teaches a method for determining the transfection of a nucleotide (in particular a plasmid) into a host cell, wherein the nucleotide is fluorescently labeled with a fluorescently labeled PNA molecule (see for example the Abstract and page 3, lines 21-28). The method of transfection is preferably a cationic lipid transfection method (see for example page 10, lines 10-21). Upon transfection of the nucleotide into the cell, the fluorescent label can be detected by fluorescence microscopy techniques, such as FRET (see for example 14-15, Example 4). The cells into which the labeled nucleotide is transfected are B16F10 and CV-1 cells (see for example page 16, lines 28-32), each of which is a transformed tumor cell line. As a result, Felgner teaches each and every element of the invention as claimed in claim 17 and 31 of the instant invention.

Claims 17, 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Zelphati et al. (IDS #2 reference E; see entire document; henceforth Zelphati).

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Zelphati teaches the fluorescent labeling of DNA using a PNA molecule that is itself fluorescently labeled (see for example the Abstract and the paragraph bridging the left and right columns of page 16). This fluorescently labeled DNA molecule is then transfected into the B16F10 and CV-1 transformed cell lines using a cationic lipid transfection method (see for example the Abstract and the paragraph bridging pages 16-17). The number of cells that contain the fluorescent label is then quantified (i.e., the number of cells containing the label is determined) using fluorescence microscopy techniques (see for example page 17, left column, third and fourth full paragraphs). As a result, Zelphati teaches each and every element of instant claims 17, 31 and 33.

Claims 17, 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Neves et al. (IDS #2 reference D; see entire document; henceforth Neves).

Neves teaches the covalent labeling of DNA with a fluorescent label (see for example the Abstract and page 52, the second and third full paragraphs). Neves further teaches taking the fluorescently labeled DNA, and transfecting it into the NIH 3T3 and CV-1 transformed cell lines using a cationic lipid transfection method (see for example the paragraph bridging the left and right columns of page 52). Following the transfection, the number of cells containing the fluorescent label was determined by fluorescence microscopy (see for example Figures 3 and 4, and their respective legends, and the paragraph bridging the left and right columns of page 53), where it was determined that 100% of the cells displayed fluorescence. As a result, Neves teaches each and every element of instant claims 17, 31 and 33.

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Allowable Subject Matter

No claims are allowable.


Claims 18-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson, Ph.D.
AU 1636


**JAMES KETTER
PRIMARY EXAMINER**